UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE WELLBUTRIN SR/ZYBAN ANTITRUST LITIGATION	)	Master File No. 02-CV-4398
THIS DOCUMENT RELATES TO:	)	
ALL ACTIONS	)	

DEFENDANTS' ANSWER TO PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

1. This litigation arises from a series of actions undertaken by Defendants GlaxoSmithKline plc, and SmithKline Beecham Corporation to unlawfully maintain their monopoly on Wellbutrin SR® ("Wellbutrin SR") and/or Zyban®. Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive, and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin SR and Zyban. In the absence of Defendants' unlawful actions, generic versions of Wellbutrin SR and/or Zyban could have been available as early as September 15, 1999.

ANSWER: Defendants GlaxoSmithKline plc and SmithKline Beecham Corporation (collectively "GSK") deny the allegations in paragraph 1.

2. Wellbutrin SR is a sustained release antidepressant drug used to treat depression. The active ingredient in Wellbutrin SR is bupropion.[1] Zyban, which has the same chemical composition as Wellbutrin SR, is marketed and sold by Glaxo for the cessation of smoking. For the 12 months ending June 30, 2002, domestic sales of Wellbutrin SR generated revenues in excess of $1.3 billion. Domestic sales of Zyban were $83 million during the same period. No generic version of

[1] Wellbutrin has the same chemical composition as Zyban®, another drug manufactured and sold by Glaxo. Wellbutrin and Zyban are the same medication and are covered by the same patent, but, as stated above, are marketed for different treatments -- antidepression and smoking cessation, respectively. Accordingly, manufacturers seeking to sell sustained release versions of bupropion for treatment of depression and also seek approval to sell generic versions of Zyban.

Wellbutrin SR or Zyban is currently marketed in the United States because Defendants have unlawfully monopolized and/or attempted to monopolize the domestic market for Wellbutrin SR and/or Zyban and their generic bioequivalents.

ANSWER: GSK admits that Wellbutrin SR is a drug used to treat depression and that Zyban is a drug used for smoking cessation, both with bupropion hydrochloride as the active ingredient. GSK admits that both are sustained release, patented products. GSK admits that no generic version of Wellbutrin SR or Zyban currently is marketed lawfully in the United States. GSK admits that gross sales for Wellbutrin SR for the twelve months ending June 30, 2002 exceeded $1.3 billion. GSK denies the remaining allegations in paragraph 2.

3. At least five manufacturers of generic drugs, including Andrx Pharmaceuticals ("Andrx"), Watson Pharmaceuticals ("Watson"), Eon Labs Manufacturing ("Eon"), Impax Laboratories ("Impax"), and Excel Pharmaceuticals ("Excel") have filed applications with the FDA requesting approval to market generic versions of Wellbutrin SR and/or Zyban. In their applications, the manufacturers assert that their products are "bioequivalent" to Wellbutrin SR and Zyban and do not infringe any patent owned by or licensed to Defendants. Because of Defendants' actions, however, no generic formulations of bupropion sustained release have been approved by the FDA. At least one generic drug manufacturer has received tentative FDA approval for the 100 and 150 mg dosages of bupropion hydrochloride extended-release tablets.

ANSWER: GSK admits on information and belief that Andrx, Watson, Eon, Impax, and Excel filed Abbreviated New Drug Applications with the FDA seeking to market generic sustained release bupropion hydrochloride products asserting that their products are bioequivalent to Wellbutrin SR and/or Zyban and do not infringe on any relevant patents, and that Eon has received tentative FDA approval. GSK denies the remaining allegations in paragraph 3.

4. Plaintiffs bring their claims on behalf of all indirect purchasers of Wellbutrin SR and/or Zyban, i.e. consumers and third-party payors, the last persons and entities

in the chain of distribution, who purchased these prescription drugs other than for resale from September 15, 1999 to the present (the "Class Period").

ANSWER: GSK admits that Plaintiffs purport to bring the action described in paragraph 4. GSK otherwise denies the allegations in paragraph 4.

5. Plaintiffs allege that Defendants have unlawfully extended their monopoly in the United States Wellbutrin SR/Zyban markets by, *inter alia***,** filing baseless patent infringement actions against manufacturers seeking to market generic versions of Wellbutrin SR and/or Zyban. As a result of their unlawful acts, Defendants have: (i) unreasonably restrained, suppressed and eliminated competition in the Wellbutrin SR and/or Zyban markets; and (2) [sic] illegally maintained their monopoly in the Wellbutrin SR and/or Zyban markets.

ANSWER: GSK admits that Plaintiffs have included in their Complaint the allegations in paragraph 5. GSK otherwise denies the allegations in paragraph 5.

6. Defendants have instituted a series of patent infringement actions (and have aggressively prosecuted these actions) which are objectively baseless and without merit for the purpose of triggering the 30-month stay and extending the time during which they enjoy complete exclusivity in the domestic market for Wellbutrin SR and Zyban. This extension of market exclusivity has allowed Defendants to stymie generic competition and reap millions of dollars in unlawful monopoly profits.

ANSWER: GSK admits that it has filed and prosecuted patent infringement actions against Andrx, Watson, Impax, Eon, and Excel. GSK denies the remaining allegations in paragraph 6.

7. Defendants' conduct has had far-ranging impact on consumers and third-party payors across the United States. The laws governing pharmaceutical products are meant to balance the competing policy goals of providing new drug innovators an economic return on their investments while also ensuring consumers access to additional and more affordable generic versions of brand-name drugs. By engaging in anticompetitive conduct to prevent generic entry, Defendants effectively forced consumers to continue paying monopoly prices for Wellbutrin SR and/or Zyban prescription products.

ANSWER: The allegations in the second sentence of paragraph 7 are legal conclusions to which no answer is required. To the extent an answer is required, GSK refers the Court to the laws governing pharmaceutical products (and the legislative history) and related federal regulations and case law. GSK denies the remaining allegations in paragraph 7.

8. As a direct and proximate result of Defendants' unlawful conduct, consumers and third-party payors throughout the United States have been denied the benefits of free and unrestrained competition in the Wellbutrin SR and Zyban markets. Specifically, purchasers have been denied the opportunity to choose between the Wellbutrin SR and Zyban brand name prescription products and generic versions of these medications which would have initially been priced 30% to 40% below Wellbutrin SR and/or Zyban.

ANSWER: GSK denies the allegations in paragraph 8.

9. Plaintiff MC-UA Local 119 Health and Welfare Plan (the "MC Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The MC Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR and Zyban. During the Class Period, the MC Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged herein.

ANSWER: GSK denies the allegation in paragraph 9 that it engaged in unlawful conduct and/or injured the MC Plan. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 and, on that basis, denies these allegations.

10. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an "employee welfare benefit plan" and "employee benefit plan." UFCW's office from which it pays medical benefits, including benefits for prescription drugs, is located in Cook County, Illinois.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 and, on that basis, denies these allegations.

11. Plaintiff Sidney Hillman Health Center of Rochester, Inc. is a multi-employer employee welfare benefit plan. During the Class Period, the Sidney Hillman Health Center was an indirect purchaser of Wellbutrin SR and/or Zyban and was injured by Defendants' unlawful conduct as alleged herein.

ANSWER: GSK denies the allegation in paragraph 11 that it engaged in unlawful conduct and/or injured the Sidney Hillman Health Center. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 and, on that basis, denies these allegations.

12. Plaintiff Health Care For All, Inc. ("HCFA") is a Massachusetts private non-private membership corporation organized under Chapter 180 of the Massachusetts laws with its principal place of business in Boston, Massachusetts. Founded in 1985, HCFA represents Massachusetts citizens on healthcare-related issues. Representing about 1,200 dues paying members, HCFA seeks healthcare reform through policy analysis, information referral, advocacy, community organization and public education. Certain HCFA members purchased Wellbutrin SR and/or Zyban in Massachusetts during the class period other than for resale and were injured by the illegal conduct alleged herein.

ANSWER: GSK denies the allegation in paragraph 12 that it engaged in unlawful conduct and/or injured HCFA or its members. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12 and, on that basis, denies these allegations.

13. Plaintiff Florida Advocates for Truth ("F.A.C.T.") is a non-profit organization, and is located in Coral Springs, Florida. F.A.C.T. has standing to bring suit for injunctive relief on behalf of its members, one or more of which has purchased and/or paid for Wellbutrin SR® (and/or Zyban® during the class period and who individually would have standing to sue in their own right.

ANSWER: GSK states that the allegation that F.A.C.T. has standing is a legal conclusion to which no answer is required. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 and, on that basis, denies these allegations.

14. Plaintiff Joseph Burrell purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 12 that it engaged in unlawful conduct and/or injured Mr. Burrell. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 and, on that basis, denies these allegations.

15. Plaintiff Eileen Jacobs purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 15 that it engaged in unlawful conduct and/or injured Ms. Jacobs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 and, on that basis, denies these allegations.

16. Plaintiff Joanne Gaddy purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 16 that it engaged in unlawful conduct and/or injured Ms. Gaddy. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 and, on that basis, denies these allegations.

17. Plaintiff Sheila A. Vigeant purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than she would have absent Defendants' unlawful in monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 17 that it engaged in unlawful conduct and/or injured Ms. Vigeant. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 and, on that basis, denies these allegations.

18. Plaintiff Jeffrey Ettinger purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 18 that it engaged in unlawful conduct and/or injured Mr. Ettinger. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 and, on that basis, denies these allegations.

19. Plaintiff Matthew Andre purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegation in paragraph 19 that it engaged in unlawful conduct and/or injured Mr. Andre. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 and, on that basis, denies these allegations.

20. GlaxoSmithKline plc is a United Kingdom corporation with its principal office located at Glaxo Wellcome House, Berkeley Avenue, Grenford, Middlesex, UB6 0NN, United Kingdom. GlaxoSmithKline was formed following the December 2000 merger of Glaxo Wellcome and SmithKline Beechman [sic].

ANSWER: GSK denies the allegations in paragraph 20. By way of further answer, GSK states that GlaxoSmithKline plc is a United Kingdom corporation with its head office and registered office located at 980 Great West Road, Brentford, Middlesex

XO TW8 9GS and clarifies that GSK was formed as a result of a December 2000 merger of Glaxo Wellcome and SmithKline Beecham.

21. SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline Inc. and is a subsidiary of GlaxoSmithKline plc (GlaxoSmithKline plc and SmithKline Beecham Corp. d/b/a GlaxoSmithKline Inc. are referred to collectively as "Glaxo").

ANSWER: GSK admits the allegations in the first sentence of paragraph 21. GSK denies the allegations in the second sentence of paragraph 21. By way of further answer, GSK states that SmithKline Beecham Corporation also conducts business in the name of GlaxoSmithKline and is a subsidiary of GlaxoSmithKline plc.

22. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief, and the costs of suit, including reasonable attorneys' fees, for injuries to Plaintiffs and members of the class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. § 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

ANSWER: GSK admits only that Plaintiffs purport to bring the claims described in the first sentence of paragraph 22. GSK denies that it violated federal antitrust laws and similarly denies that Plaintiffs or members of the putative class suffered any injuries as a result of such alleged violations. The allegations in the second and third sentences are legal conclusions that require no answer. To the extent an answer is required, GSK denies the remaining allegations in paragraph 22.

23. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) because Defendants reside, transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

ANSWER: The allegations in paragraph 23 are legal conclusions that require no answer. To the extent an answer is required, GSK admits only that venue is proper. GSK denies the remaining allegations of paragraph 23 on the grounds that the term "substantial" is inherently vague and ambiguous.

24. Plaintiff bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, specifically Rules 23(b)(2) and 23(b)(3), on behalf of the following class (the "Class):

> All persons and entities in the United States who, at any time from September 15, 1999 until present indirectly purchased Wellbutrin SR and/or Zyban in the United States other than for re-sale. Excluded from the Class are the Defendants, their subsidiaries and affiliates, government entities and any person or entity that purchased Wellbutrin SR and/or Zyban directly from Defendants. For purposes of the Class definition, persons and entities "purchased" Wellbutrin SR and/or Zyban if they paid some or all of the purchase price.

ANSWER: GSK admits only that the Plaintiffs purport to bring this action under the rules mentioned in paragraph 24 and as representatives of the putative class described in that paragraph. The allegations of paragraph 24 are otherwise legal conclusions that require no answer. To the extent an answer is required, GSK denies the remaining allegations in paragraph 24.

25. Plaintiffs believe, and therefore aver, that there are thousands of members in the above-described class; their exact number and identities being currently unknown to Plaintiffs, but known to Defendants and/or ascertainable from appropriate discovery.

ANSWER: GSK admits that the numbers of members in the putative class described in paragraph 24 is at least in the thousands. GSK is without sufficient knowledge or information to form a belief as to the truth of whether Plaintiffs know the

number and identities of the putative class members and, on that basis, denies this allegation. GSK denies the remaining allegations in paragraph 25.

26. Among the questions of law and fact common to the Class are:

(a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Wellbutrin SR and/or Zyban;

(b) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Wellbutrin SR and/or Zyban;

(c) Whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Wellbutrin SR and/or Zyban to be maintained at supracompetitive levels;

(d) Whether Defendants' patent infringement lawsuits against horizontal competitors and potential competitors that have filed ANDAs for generic Wellbutrin SR and/or Zyban constitute unlawful conduct;

(e) Whether the Class suffered and continues to suffer antitrust injury; and

(f) Whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

ANSWER: GSK states that the allegations in paragraph 26 are legal conclusions that require no answer. To the extent an answer is required, GSK denies the allegations in paragraph 26.

27. Plaintiffs' claims are typical of the Class because Plaintiffs and all members of the Class were injured and continue to be injured in the same manner by Defendants' unlawful, anticompetitive and inequitable methods, acts and practices, and wrongful conduct in the conspiracies complained of herein, *i.e.*, they have paid supra-competitive and artificially high prices for Wellbutrin SR and/or Zyban and will continue to be forced to do so until the markets for Wellbutrin SR and/or Zyban are competitive.

ANSWER: GSK states that the allegations of typicality in paragraph 27 are legal conclusions that require no answer. GSK denies the remaining allegations in paragraph 27.

28. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class.

ANSWER: GSK is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 28 and, on that basis, denies these allegations. GSK also states that the allegations in paragraph 28 are legal conclusions that require no answer.

29. The questions of law and fact common to the members of the Class predominant over any questions which may affect only individual members.

ANSWER: GSK denies the allegations in paragraph 29. GSK further states that the allegations in paragraph 29 are legal conclusions that require no answer.

30. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation.

ANSWER: GSK denies the allegations in paragraph 30. GSK further states that the allegations in paragraph 30 are legal conclusions that require no answer.

31. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

ANSWER: GSK denies the allegations in paragraph 31. GSK further states that the allegations in paragraph 31 are legal conclusions that require no answer.

32. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. In 2001, sales of prescription drugs dispensed in the United States were approximately $153 billion.

ANSWER: GSK denies the allegations in paragraph 32 on the grounds that the terms "most profitable" and "sales" are inherently vague and ambiguous.

33. Sales of Wellbutrin SR and Zyban generated in excess of $l.1 billion in worldwide revenues in 200l, a substantial portion of which were derived from sales in the United States.

ANSWER: GSK admits that the 2001 worldwide gross sales of Wellbutrin SR and Zyban exceeded $1.1 billion. GSK denies the remaining allegations in paragraph 33 on the grounds that the term "substantial" is inherently vague and ambiguous.

34. Under the Federal Food, Drug, and Cosmetic Act, 21 US.C. § 301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("ANDA") [sic] with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585**,** codified at 21 U.S.C. § 355(j*)* (the "Hatch-Waxman Act") and 35 U.S.C. § 271(e).

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegation that "[n]ew drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents," and, on that basis, denies this allegation. GSK states that the remaining allegations of paragraph 34 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as amended by the Drug Price Competition and Patent Restoration Act of 1984 (the

"Hatch-Waxman" Act), federal patent statutes (e.g., 35 U.S.C. 101 et sec) and related federal regulations and case law.

35. In addition to information on safety and efficacy, NDA applicants must submit the FDA a list of all patents that claim the drug for which FDA approval is being sought, or that claim a method of using that drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

ANSWER: GSK states that the allegations of paragraph 35 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

36. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), where it can be easily found and consulted by future FDA applicants.

ANSWER: GSK admits only that *Approved Drug Products with Therapeutic Equivalence Evaluations* is commonly called the Orange Book. GSK states that the remaining allegations in paragraph 36 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

37. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer obtains a new patent that claims the drug or methods of its use, the company must supplement its NDA by submitting information on the new patent within 30 days of issuance. The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders, and to withhold its approval of a subsequent drug application, whenever the patent holder presents a litigated dispute (baseless or not) regarding the validity or infringement of the patent. If an unscrupulous patent holder provides false information to the FDA or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 concerning how the FDA conducts itself and, on that basis, denies these allegations. GSK also states that the remaining allegations in paragraph 37 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, federal patent statutes (e.g., 35 U.S.C. 101 et sec), and related federal regulations and case law.

38. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, it turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug that has been approved by the FDA is available.

ANSWER: GSK states that the allegations in paragraph 38 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, related federal regulations and case law, and individual state laws regarding prescriptions and generic substitution.

39. Generic drugs are drugs that the FDA has found to be bioequivalent to brand name drugs, *i.e.*, generic drugs have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

ANSWER: GSK states that the allegations in paragraph 39 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA and related federal regulations and case law.

40. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and

quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 15% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales. Unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 and, on that basis, denies these allegations. GSK also denies the allegations in paragraph 40 on the ground that it uses terms that are inherently vague and ambiguous, such as "invariably," "typically," "substantial," and "significant."

41. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing either the branded drug, or the AB-rated generic at a lower price.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 and, on that basis, denies these allegations. GSK also denies the allegations in paragraph 41 on the ground that it uses the term "most" that is inherently vague and ambiguous. GSK also states that the allegations in paragraph 41 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the applicable state laws regarding prescriptions and generic substitution.

42. Once a physician writes a prescription for a brand-name drug such as Wellbutrin that prescription defines and limits the market to the drug named or its AB-rated

generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

ANSWER: GSK states that the allegations in paragraph 42 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the applicable state laws regarding prescriptions and generic substitution.

43. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Many health insurance companies and employee benefit plans encourage or require substitution of generic drugs for brand-name drugs in order to lower health care costs. Retail pharmacies routinely substitute generic drugs for brand-name drugs whenever possible in order to lower their own costs and the cost of their customers.

ANSWER: GSK denies the allegations in the first sentence of paragraph 43. GSK further denies the allegations in paragraph 43 on the ground that it uses terms that are inherently vague and ambiguous, such as "many" and "routinely." Further, GSK is without sufficient knowledge or information to form a belief as to the truth of the allegations in the second and third sentences in paragraph 43, and on that basis, denies these allegations.

44. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development, approval and marketing of generic drugs. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an "abbreviated" new drug application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original, "pioneer" drug. The Act also provides an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug – *i.e.*, a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from other generic competition.

ANSWER: GSK states that the allegations in paragraph 44 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the

text of the FDCA, the Hatch-Waxman Act (and its legislative history), and related federal regulations and case law.

45. The most important new information that must be included in the ANDA concerns the generic company's position vis-a-vis the patent that the pioneer manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications to the FDA:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent (or patents) for the pioneer drug has (or have) expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id*. If the generic manufacturer makes a Paragraph IV Certification, the ANDA applicant must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. *See* 21 U.S.C. § *355*(j)(2)(A)(vi)(IV).

ANSWER: GSK denies the allegations in the first sentence of paragraph 45 on the ground that it uses terms that are inherently vague and ambiguous, such as "most important." GSK further states that the allegations in paragraph 45 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

46. The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day statutory period in which to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by

patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the generic drug is automatically postponed until the earliest of: (i) the expiration of the patent; (ii) thirty months from the patent holder's receipt of the Paragraph IV Certification (30-month stay); or (iii) a final judicial determination of invalidity or non-infringement from which no appeal can be or has been taken. *Id.*; 21 C.F.R. § 314.107.

ANSWER: GSK denies the allegations in the third sentence of paragraph 46. GSK states that the remaining allegations in paragraph 46 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

47. Under 21 U.S.C. § 355(j)(5)(B)(iv), the first applicant to submit an ANDA with Paragraph IV Certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. The 180-day exclusivity period begins when the first ANDA applicant (a) either begins selling the generic drug or (b) obtains a final judgment of non-infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers. If, however, the patent holder is able to forestall the events which trigger the start of the 180-day period of exclusivity, it can delay indefinitely the entry of all generic competition.

ANSWER: GSK states that the allegations in paragraph 47 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

48. Bupropion hydrochloride is an antidepressant used in the treatment of depression that is no longer subject to an extant patent. On June 25, 1974, the United States Patent and Trademark Office issued U.S. Patent No. 3,819,706 (the " '706 Patent"), granting to a predecessor of Defendants a compound patent on bupropion.

ANSWER: GSK admits that bupropion hydrochloride is covered by the '706 Patent. GSK denies the remaining allegations in paragraph 48.

49. In the mid-1980s, the FDA granted to Defendants' predecessor approval to manufacture, market and sell bupropion hydrochloride under the brand name Wellbutrin™ ("Wellbutrin"). Defendants' predecessors thereafter began the manufacture, marketing and sale of Wellbutrin.

ANSWER: GSK admits the allegations in paragraph 49. By way of further answer, GSK states that it began marketing Wellbutrin in the United States in 1989 and that this was the immediate release Wellbutrin, not the sustained release Wellbutrin SR that is the subject of the Consolidated Complaint.

50. At that time, bupropion hydrochloride, or Wellbutrin, was sold in the form of an instant release tablet in which more than 75% of the bupropion was released from the tablet into dissolution media within about forty-five minutes. Given the instant release of bupropion, it was necessary for a patient to take Wellbutrin three or four times a day.

ANSWER: GSK denies the allegations in the first sentence of paragraph 50 as vague. By way of further answer, GSK states that immediate-release Wellbutrin is approved for dosing three times a day.

51. The '706 Patent expired in mid-1991. By that time, and for years before then, Defendants' predecessors had enjoyed a monopoly on the sale of bupropion through the manufacture, marketing and sale of Wellbutrin.

ANSWER: GSK admits the allegation in the first sentence in paragraph 51. GSK denies the remaining allegations in paragraph 51 in part on the ground that it uses terms that are inherently vague and ambiguous, such as "for years."

52. "Although bupropion has been off-patent for almost ten (10) years Glaxo has continued a monopolization of the market through patents on sustained-release formulations which eliminate the need to take bupropion three or four times a day." *See Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*, 190 F. Supp. 2d 1354, 1357 (S.D. Fla. 2002).

ANSWER: GSK admits that the allegation in paragraph 52 purports to quote a select portion of the decision in Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.,

190 F. Supp. 2d 1354, 1357 (S.D. Fla. 2002), but further states that the select text is quoted inaccurately. GSK denies the substance of the allegations in paragraph 52.

53. Subsequent to expiration of the '706 Patent, Defendants developed a sustained release version of bupropion which it markets as Wellbutrin SR. This formulation allows users of the drug to treat depression with only one or two daily doses.

ANSWER: GSK denies the allegations in the first sentence of paragraph 53 as vague. By way of further answer, GSK states that Wellbutrin SR and/or Zyban are approved for dosing one to two times a day.

54. In August 1993, Defendants' predecessor filed an application with the PTO for a controlled sustained release tablet containing bupropion (the "1993 SR Application").

ANSWER: GSK admits the allegations in paragraph 54.

55. The 1993 SR Application (as well as the patent that ultimately issued from that application) describes a sustained-release formulation of bupropion by combining bupropion with hydroxypropyl methylcellulose ("HPMC"). HPMC is an excipient (that is, an inert ingredient or substance added to a prescription to give the desired consistency or form) that is available in many different grades ranging from (i) high viscosity, high molecular weight polymer that forms a release-controlling hydrogel to a (ii) low viscosity, low molecular weight HPMC grade commonly known and widely used in the industry as a main component of instant release film coatings.

ANSWER: GSK admits that it applied for and was issued United States Patent No. 5,427,798 and states that the relevant patent application speaks for itself regarding the invention disclosed and claimed therein. GSK denies the remaining allegations in the second sentence of paragraph 55.

56. The 1993 SR Application described only the use of the high viscosity, high molecular weight polymer form of HPMC as the controlling agent for the sustained-release functionality.

ANSWER: GSK denies the allegations in paragraph 56.

57. In addition, the proposed independent claims and specification of the 1993 SR Application indicated that the contemplated use of HPMC was to control the release rate of bupropion hydrochloride into the bloodstream.

ANSWER: GSK admits the allegations in paragraph 57.

58. The prosecution of the 1993 SR Application made evident the need for all claims to focus on, and be limited by, the significant role that HPMC played in the invention (i.e. use of high density, high molecular weight HPMC to control the release rate).

ANSWER: GSK denies the allegations in paragraph 58.

59. On April 13, 1994, the examiner rejected Claims Fourteen, Fifteen and Nineteen of the Application for lack of enablement. Specifically the examiner wrote:

> The rate of release is directly related to the release retarding effect of hydroxypropyl methylcellulose. While other excipients have been disclosed, *the particular cellulose is considered critical for controlled and/or sustained release and should be incorporated into the independent claims.* The disclosure of a single species does not provide a basis for disclosing a generic concept. . . (emphasis added).

ANSWER: GSK admits that this purports to be a quote from the office action, but denies the allegation in paragraph 59 to the extent it is taken out of context as well as inaccurately quoted. By way of further answer, GSK refers the Court to the office action.

60. In response, Defendants amended Claims Fourteen and Fifteen to recite that the tablets required HPMC. Defendants failed to amend Claims Eighteen and Nineteen at that time, but these claims were later amended by the examiner to identify the use of HPMC as the means for releasing bupropion.

ANSWER: GSK denies the allegations in paragraph 60. By way of further answer, GSK refers the Court to the office action.

61. Moreover, Defendants proposed Claim One in the 1993 Application did not contain any recitations regarding bupropion release. The examiner therefore rejected this Claim for lack of enablement as well, noting that the claim needed to be limited:

> [A]pplicants are claiming a tablet that provides *a distinct release profile.* The advantage provided by the unique tablet *differ [sic] from the instant release tablet. The limitations of claims 2-3 are considered critical and should be incorporated into claim 1 for proper enablement*. (emphasis added).

ANSWER: GSK denies the allegations in paragraph 61. By way of further answer, GSK refers the court to the office action.

62. In response, Defendants made similar amendments to Claim One, limiting it with the release controlling language.

ANSWER: GSK denies the allegations in paragraph 62.

63. The examiner's initial assessment of the 1993 SR Application was that the prior release controlling language in Claims One, Fourteen, Fifteen, Eighteen and Nineteen was too broad. By amending these claims (and indeed, by being forced to amend these claims), Defendants acknowledged and conceded that HPMC was the "particular cellulose that is critical for the controlled release of the tablets" and that the high density, high viscosity HPMC was an integral part of the patented product.

ANSWER: GSK denies the allegations in paragraph 63.

64. The PTO later mailed an Examiner's Amendment, which was authorized by counsel for Defendants, adding an HPMC limitation to another two claims in the '798 Patent. The PTO also issued a Notice of Allowability, signifying that the PTO's previous rejection of the claims would be withdrawn based on the addition of the HPMC limitation.

ANSWER: GSK denies the allegations in paragraph 64. By way of further answer, GSK refers the Court to the Examiner's Amendment and Notice of Allowance.

65. Based on the prosecution history, including the examiner's analysis and the compulsory amendments, it was clear that the ultimate patent would cover only high density, high viscosity HPMC as a control release agent.

ANSWER: GSK denies the allegations in paragraph 65.

66. On June 27, 1995 – after the claims in the 1993 SR Application had been limited during patent prosecution – the PTO issued Patent No. 5,427,798 (the " '798 Patent") entitled "Controlled sustained release tablets containing bupropion." The '798 Patent was issued to Defendants' predecessor.

ANSWER: GSK denies that its claims in the '798 patent had been "limited during patent prosecution," but otherwise admits the allegations in paragraph 66.

67. Glaxo describes the sustained release tablet claimed in the '798 Patent as follows:

> A controlled sustained release tablet having at least one year shelf life and containing bupropion hydrochloride, hydroxypropyl methylcellulose and cystein hydrochloride or glycine hydrochloride with the tablet having a surface area to volume ratio to effectively control bupropion hydrochloride release in the body.

ANSWER: GSK denies the allegations in paragraph 67. By way of further answer GSK refers the Court to the '798 Patent.

68. The patent specifications and patent prosecution history make clear that the '798 Patent is a narrow patent claiming a specific form of extended release tablet of bupropion which incorporates the high viscosity, high polymer weight form of the excipient hydroxpropyl methylcellulose ("HPMC") as a control release agent.

ANSWER: GSK denies the allegations in paragraph 68.

69. Also clear both from the nature of the claims made in the '798 Patent, as well as from the patent prosecution history, is that HPMC as a release control agent is critical to the sustained release technology claimed by the '798 Patent.

ANSWER: GSK denies the allegations in paragraph 69.

70. Indeed, in its *"Brief Statement of Invention,"* Glaxo notes that the purpose for the presence of HPMC is for "controlling drug release rate."

ANSWER: GSK admits the allegations in paragraph 70 quote from the '798 Patent but denies the allegation in paragraph 70 to the extent it is taken out of context.

By way of further answer, GSK refers the Court to the '798 Patent.

71. Several manufacturers of generic drugs have filed ANDAs with the Food and Drug Administration seeking authorization to market generic versions of Wellbutrin SR. The companies include Andrx, Eon, Impax, Excel and Watson.

ANSWER: GSK admits that Andrx, Eon, Impax, Excel and Watson filed ANDAs seeking to market generic versions of Wellbutrin SR. GSK otherwise denies the allegations in paragraph 71.

72. While the patent claiming bupropion expired more than ten years ago, the '798 Patent claiming bupropion with HPMC in a sustained release formulation is still valid.

ANSWER: GSK admits that the '706 Patent expired in 1991 and that the '798 Patent is a valid patent that has not yet expired but otherwise refers the Court to the '706 and '798 Patents for what they claim. GSK otherwise denies the allegations in paragraph 72 as vague.

73. Because utilization of the sustained release technology patented by Glaxo would constitute infringement of the '798 Patent, the above-referenced generic drug manufacturers have sought approval to market generic versions of Wellbutrin SR that utilized different sustained release formulations.

ANSWER: GSK admits that utilization of GSK's patented invention would constitute infringement of the '798 Patent. GSK denies the remaining allegations in paragraph 73.

74. In each case, the generic drug manufacturer's ANDA seeks approval of a bupropion sustained release tablet that does not use HPMC as a control release agent and therefore would not infringe upon any valid patent.

ANSWER: GSK denies the allegations in paragraph 74.

75. In August 1999, Andrx submitted two ANDAs with the FDA seeking approval to market a sustained release bupropion tablet as a generic version of Wellbutrin SR and Zyban.

ANSWER: GSK admits that Andrx submitted ANDAs with FDA seeking to market generic versions of Wellbutrin SR and Zyban. GSK denies the remaining allegations in paragraph 75.

76. Andrx included paragraph IV certifications in its ANDAS, claiming that the medication did not infringe Glaxo's '798 Patent because Andrx's form of bupropion employed a release control technology that was different from Glaxo's sustained release formulation. Specifically, Andrx sought approval of a bupropion tablet with release control technology that allows for diffusion through the Eudragit and Ethocel membranes.[2]

ANSWER: GSK admits that it received notification from Andrx that it had included a Paragraph IV certification in its ANDA application claiming that its medication did not infringe GSK's patent. GSK denies the remaining allegations in paragraph 76.

77. Indeed, not only did Andrx seek approval from the FDA on the basis that its bupropion sustained release technology was different, it also sought to patent its release control process.

ANSWER: GSK denies the allegations in paragraph 77.

78. Andrx submitted an application to the PTO for a patent claiming its sustained release formulation. Andrx's application listed the '798 Patent as a prior art reference, but maintained that its release control technology was unique and that a patent should be issued over the '798 patent.

ANSWER: GSK denies the allegations in paragraph 78. By way of further answer, GSK refers the Court to the Andrx patent application.

79. On April 3, 2001, the examiner in the PTO reviewing Andrx's patent application agreed, calling the release control technology in Andrx's form of bupropion

[2] Andrx's release control formulation involves sealing separate pellets with a sustained release coating made from a layered combination of Eudragit E100 and Ethocel 100.

"distinctly different from the form of bupropion covered by Glaxo's '798 Patent. Andrx was subsequently issued. U.S. Patent No. 6,210,716 (the " '7l6 Patent").

ANSWER: GSK denies the allegations in paragraph 79.

80. Eon submitted ANDA 75-932 in July 2000 seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 and, on that basis, denies these allegations.

81. Eon's ANDA included a Paragraph IV Certification with regard to the '798 Patent claiming that its medication did not infringe on Glaxo's patent.

ANSWER: GSK admits that it received notification from Eon that it had included a Paragraph IV certification in its ANDA application claiming that its medication did not infringe GSK's patent.

82. Eon's Paragraph IV Certification of non-infringement was predicated on the fact that its bupropion sustained release tablet did utilize the HPMC release technology patented by Glaxo, but rather contained hydroxypropyl cellulose ("HPC") as a control release agent.

ANSWER: GSK denies the allegations in paragraph 82.

83. On January 4, 2002, Eon received tentative approval by the FDA to market its generic version of Wellbutrin SR and Zyban utilizing the HPC sustained release formulation.

ANSWER: GSK admits that in January 2002 FDA granted Eon tentative approval for its ANDAs for generic versions of Wellbutrin SR and Zyban. GSK denies the remaining allegations in paragraph 83.

84. IMPAX Laboratories submitted an ANDA in August 2000 seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84 and, on that basis, denies these allegations.

85. Like Eon's ANDA, IMPAX's ANDA included a Paragraph IV Certification with regard to the '798 Patent which was predicated on the fact that IMPAX's proposed bupropion sustained release tablet utilized HPC as a control release agent, not HPMC.

ANSWER: GSK admits that it received notification from Impax that it had included a Paragraph IV certification in its ANDA application claiming that its medication did not infringe GSK's patent. GSK denies the remaining allegations in paragraph 85.

86. In October 2001, Excel Pharmaceuticals submitted an ANDA seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 and, on that basis, denies these allegations.

87. In its ANDA, Excel represented to the FDA all of the ingredients that would be included within its generic version of Wellbutrin SR.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 and, on that basis, denies these allegations.

88. Excel's ANDA identified that its bupropion sustained release tablet would use the polymer polyvinyl alcohol ("PVA") to control the release rate of bupropion hydrochloride into the bloodstream, not HPMC. Based on this, Excel properly certified its belief that the bupropion sustained release tablet it proposed to market would not infringe upon Glaxo's '798 Patent.

ANSWER: GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 88 and, on that basis, denies these allegations. GSK denies the allegations in the second sentence in paragraph 88.

89. Although several generic drug manufacturers have sought and/or received tentative approval to market bioequivalent generic versions of Wellbutrin SR and/or Zyban in the United States, and although the products for which approval has been received do not infringe upon any current patent, these generics cannot come to the market because of Defendants' unlawful and anticompetitive conduct. This conduct includes the filing of baseless lawsuits seeking to enjoin the generic manufacturers from producing bioequivalent generic versions of Wellbutrin SR and/or Zyban on the grounds that these generics infringe upon Defendants' 798 Patent claiming bupropion sustained release tablets.

ANSWER: GSK denies the allegations in paragraph 89.

90. The filing of a patent infringement action triggers a 30-month stay on the sale of generic versions pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay is triggered irrespective of whether there is any likelihood of success, or even merit, to the patent infringement action.

ANSWER: GSK states that the allegations in paragraph 90 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the text of the FDCA, the Hatch-Waxman Act, and related federal regulations and case law.

91. Defendants have instituted a series of patent infringement actions that are objectively baseless and without merit for the purpose of triggering the 30-month stay and extending the time during which they enjoy complete exclusivity in the domestic market for Wellbutrin SR and Zyban. This extension of market exclusivity has allowed Defendants to stymie genetic competition and reap millions of dollars in unlawful monopoly profits.

ANSWER: GSK denies the allegations in paragraph 91.

92. Glaxo has aggressively prosecuted the patent infringement actions in seeking to maintain their hold on the Wellbutrin SR market.

ANSWER: GSK denies the allegations in paragraph 92.

93. Defendants lawsuits pressed the scope of the '798 Patent. In commencing the actions, Defendants ignored the very limitations Defendants [sic] that had been discussed and rejected during prosecution of the patent, and Defendants knew that the allegations of infringement they were making were frivolous.

ANSWER: GSK denies the allegations in paragraph 93.

94. On September 15, 1999, Glaxo filed the first of a series of patent infringement actions involving sustained release bupropion hydrochloride against Andrx Pharmaceuticals Inc. Glaxo alleged that Andrx's proposed generic bioequivalent to Wellbutrin SR infringes upon the '798 Patent. The filing of this action triggered the 30-month stay.

ANSWER: GSK denies that it filed a "series" of patent infringement actions involving sustained release bupropion hydrochloride against Andrx. GSK admits that it filed a patent infringement action on September 15, 1999 against Andrx and admits the allegations in the second and third sentences in paragraph 94.

95. As set forth above, Andrx claimed that its version of bupropion sustained release tablets utilized a release profile distinct from that claimed by the Glaxo '798 Patent.

ANSWER: GSK denies the allegations in paragraph 95.

96. On April 3, 2001, the PTO provided a ruling essential to the resolution of Glaxo's baseless patent infringement suit. Specifically, the PTO found that Andrx's sustained release technology was "distinctly different" from the high viscosity HPMC formulation claimed by the '798 Patent.

ANSWER: GSK denies the allegations in paragraph 96.

97. Despite the PTO's finding, Glaxo (undeterred and determined to preserve its market exclusivity for as long as possible) continued with the patent litigation until February 28, 2002, when the United States District Court for the Southern District of Florida ruled that Andrx's Paragraph IV Certification was accurate: Andrx's version of sustained release bupropion hydrochloride was distinctly different from Wellbutrin SR and did not infringe Glaxo's '798 Patent.

ANSWER: GSK admits that on February 28, 2002 the United States District Court for the Southern District of Florida granted summary judgment for Andrx. GSK denies the remaining allegations in paragraph 97.

98. Glaxo has appealed the Southern District of Florida's ruling in an attempt to preserve its market exclusivity and to dissuade Andrx from bringing its product to market.

ANSWER: GSK admits that it appealed the Andrx summary judgment decision. GSK denies the remaining allegations in paragraph 98.

99. On September 28, 2000, Glaxo sued IMPAX in the Northern District of California for infringement of its '798 Patent.

ANSWER: GSK admits the allegations in paragraph 99.

100. IMPAX countered by arguing that its product does not use the HPMC sustained release technology patented by Glaxo, and moved for summary judgment on the grounds that the prosecution history precluded Glaxo from trying to claim HPC as being covered by the '798 Patent.

ANSWER: GSK denies the allegations in paragraph 100 on the grounds that the term "sustained release technology" is vague and ambiguous.

101. By amending the general means-function language originally included in the '798 Patent with a more specific HPMC limitation, Glaxo surrendered all equivalents of which it was or should have been aware and prosecution history estoppel barred infringement by the doctrine of equivalents. Summary judgment was therefore granted to IMPAX on August 21, 2002.

ANSWER: GSK admits that the Impax Court granted summary judgment for Impax on August 21, 2002. GSK denies the remaining allegations in paragraph 101.

102. The Court rejected Glaxo's argument that it did not surrender claims to an HPC equivalent because it failed to test HPC as an alternative excipient in the bupropion sustained release tablets. The Court found that one skilled in the art would, at the time the '798 Patent was being prosecuted, have known of the

similarities between HPMC and HPC; and that plaintiff's failure to conduct the necessary analysis was unreasonable.

ANSWER: GSK denies the allegations in paragraph 102 and states that the Impax Court's opinion speaks for itself.

103. The Court also placed significance on the fact that Glaxo had obtained a patent for a sustained-release formulation comprised of both HPC and HPMC in January 1990. This fact would seriously undermine any claim that Glaxo was unaware of HPC as a control release agent to have included it in an amending the '798 Patent.

ANSWER: GSK denies the allegations in paragraph 103 and states that the Impax Court's opinion speaks for itself.

104. Glaxo has appealed the Northern District of California's ruling in an attempt to preserve its market exclusivity and to dissuade IMPAX from bringing its product to market.

ANSWER: GSK admits that it has appealed the Impax decision. GSK denies the remaining allegations in paragraph 104.

105. On January 25, 2002, Glaxo brought a patent infringement suit in the Eastern District of Virginia against Excel, claiming that Excel's bupropion sustained release tablets infringed upon the '798 Patent.

ANSWER: GSK admits the allegations in paragraph 105.

106. The Court found persuasive the reasoning employed by Judge Ferguson in Glaxo's action against Andrx, and granted summary judgment to Excel on August 2, 2002.

ANSWER: GSK admits that the Excel Court stated that it found persuasive the reasoning employed by Judge Ferguson in Glaxo's action against Andrx, and granted summary judgment to Excel on August 2, 2002. GSK denies the implication that the summary judgment opinion is based on the reasoning of the Andrx court.

107. Specifically, the Court found that Excel's generic version of Wellbutrin SR, utilizing polyvinyl alcohol (PVA) as a control release agent, did not literally infringe Glaxo's patent covering HPMC.

ANSWER: GSK admits that the Excel Court found the Excel product did not infringe, but states that the Excel Court's opinion speaks for itself.

108. The Court further held that, as with HPC, one skilled in the art could have drafted amendments to the claims in the '798 Patent to include PVA. As a result, prosecution history estoppel barred Glaxo from claiming PVA under the doctrine of equivalents.

ANSWER: GSK denies the allegations in paragraph 108.

109. Glaxo has appealed the Eastern District of Virginia's ruling in an attempt to preserve its market exclusivity and to dissuade Andrx from bringing its product to market.

ANSWER: GSK admits that it has appealed the Excel decision. GSK denies the remaining allegations in paragraph 109.

110. Glaxo sued Eon Labs in the Southern District of New York claiming that Eon's generic Wellbutrin SR infringed the '798 Patent.

ANSWER: GSK admits that it sued Eon Labs in the Southern District of New York claiming that if marketed, Eon's generic Wellbutrin SR would infringe the '798 Patent.

111. Eon has argued that its bupropion sustained release tablets, containing HPC as a control release agent, does not infringe the '798 Patent.

ANSWER: GSK admits the allegations in paragraph 111.

112. The Court denied Eon's motion for partial summary judgment, finding that "[h]owever convincing Eon's arguments may be," an issue of fact exists with respect to the foreseeability of HPC as a sustained release agent.

ANSWER: GSK admits the allegations in paragraph 112, but states that the quote from the Eon Court's opinion is taken out of context and that the Eon Court's opinion speaks for itself.

113. The Court, however, also denied Glaxo's motion for partial summary judgment noting that (i) the Court has not yet resolved the issue of the existence of patent prosecution estoppel (which, as the Court in *Glaxo v. IMPAX* held on the very same issue, would bar Glaxo from seeking an adjudication of infringement under the doctrine of equivalents); and (ii) the parties have not briefed the issue of equivalence.

ANSWER: GSK denies the allegations in paragraph 113.

114. In addition to Andrx, IMPAX, Eon and Excel, Watson Laboratories, Inc. submitted an ANDA seeking FDA approval to sell generic Wellbutrin SR.

ANSWER: GSK admits the allegations in paragraph 114.

115. Glaxo received notice of Watson's ANDA on October 26, 1999 and filed a patent infringement lawsuit against Watson on December 2, 1999.

ANSWER: GSK admits that it received notice of a Paragraph IV Certification from Watson on or about October 26, 1999 and filed a patent infringement lawsuit against Watson on December 2, 1999. GSK denies the remaining allegations in paragraph 115.

116. Glaxo settled its patent infringement lawsuit against Watson in July 2001. Documents relating to the settlement and/or discontinuation of the action were filed under Seal and are not publicly available.

ANSWER: GSK admits that it settled patent infringement lawsuits against Watson in July 2001. GSK admits the second sentence in paragraph 116. By way of further answer, GSK states that pursuant to the applicable protective order, it has produced material related to the Watson patent infringement lawsuits, including the settlement documents, to Plaintiffs in this action.

117. The acts and practices of Defendants, as herein alleged, had the purpose and effect of injuring competition by preventing the entry of generic Wellbutrin SR and/or Zyban product into the relevant market. Defendants exclusionary conduct unlawfully protected Wellbutrin SR and/or Zyban from generic competition during the class period.

ANSWER: GSK denies the allegations in paragraph 117.

118. But for Defendants' illegal conduct, a generic competitor would have begun marketing a generic version of Wellbutrin SR and/or Zyban as early as September 15, 1999.

ANSWER: GSK denies the allegations in paragraph 118.

119. Defendants have engaged in monopolistic practices concerning Wellbutrin SR and Zyban to avoid a loss in market share and revenues that would inevitably result following the introduction to the market of a competing generic product.

ANSWER: GSK denies the allegations in paragraph 119.

120. Indeed, Defendants have corporate policies to extend and abuse the legitimate range of U.S. patent laws, and Defendants' attempted extension of the Wellbutrin SR/Zyban monopoly is part of the pattern and practices of Defendants. For instance, the Federal Circuit Court of Appeals recently affirmed a District Court verdict that Defendants' patent for the anti-inflammatory prescription drug nabumetone – which it markets under the brand-name Relafen – was invalid. *In re '639 Patent Litig.*, 154 F. Supp. 2d 157 (D. Mass. 2001), *aff'd sub nom., Smithkline Beecham Corp. v. Copley Pharm.*, 2002 U.S. App. LEXIS 16594 (Fed. Cir. Aug. 15, 2002). In that case, the District Judge found that Beecham had "engaged in a pattern of misrepresentations in its dealings with the PTO so pervasive as to negate any possibility that Beecham's misrepresentation to the PTO were inadvertent "loose language" or otherwise "negligently made." *Id.* at 66. The Court there also found Beecham' s witnesses "to be inconsistent, evasive and, many times, implausible." *Id.* at 193-94. The Court further found that Beecham was attempting to persuade the PTO that there was no prior art anticipating its patent, while evidence before the Court revealed that Defendant's patent department knew this was not the case, and could not believe their success in getting the patent approved, and were happy that they had "put one over on" the PTO. *Id.* at 194.

ANSWER: GSK denies the allegations in the first sentence of paragraph 120.

GSK admits that the Court of Appeals affirmed the district court's ruling on invalidity of

the '639 patent but denies the implication that that ruling relates in any way to or addresses an example of "corporate policies to extend and abuse the legitimate range of U.S. patent laws." To the extent the remainder of paragraph 120 quotes from the district court opinion in In re '639 Patent Litigation, GSK admits that paragraph 120 accurately quotes the opinion but further states that the quotations are taken out of context. By way of further answer, GSK states that to the extent that paragraph 120 paraphrases the opinion, GSK denies that the paraphrasing is accurate and states that the opinion is the best evidence of its contents. To the extent that paragraph 120 implies that the quoted or paraphrased portions of the district court opinion were affirmed by the Court of Appeals, the allegation is denied. To the contrary, GSK further states that the Court of Appeals addressed invalidity only and specifically declined to address inequitable conduct.

121. If a generic competitor had been able to enter the relevant market and compete with Defendants, consumers and third-party payors such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for Wellbutrin SR and/or Zyban products. Pharmacists generally are permitted, and in many instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

ANSWER: GSK denies the allegations in the first sentence of paragraph 121. The allegations in the second sentence of paragraph 121 are legal conclusions that require no answer. To the extent an answer is required, GSK refers the Court to the applicable state laws regarding prescriptions and generic substitution. GSK denies the remaining allegations in paragraph 121 on the grounds that it uses terms that are inherently vague

and ambiguous, such as "ready market," "quickly," "efficiently," "substantial," and "significant."

122. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the other Class members in their business or property by causing them to pay more for Wellbutrin SR and/or Zyban products than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs and other members of the Class of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

ANSWER: GSK denies the allegations in paragraph 122.

123. At all times relevant herein, Defendants manufactured and sold substantial amounts of Wellbutrin SR and Zyban in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States as follows:

- Defendants transmitted funds as well as contracts, bills, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Wellbutrin SR and Zyban; and
- Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines as well as means of interstate and international travel.

ANSWER: GSK denies the allegations in paragraph 123 on the grounds that it uses terms that are inherently vague and ambiguous, such as "all times relevant" and "substantial." GSK admits that it has manufactured and sold Wellbutrin SR and Zyban across state lines throughout the United States since 1996 and 1997, respectively, and that GSK transmitted funds as well as contracts, bills, and other forms of business communications and transactions across state and national lines in connection with the sale of Wellbutrin SR and Zyban. GSK denies the remaining allegations in paragraph 123.

124. The illegal monopolization and attempt to monopolize the markets for Wellbutrin SR and Zyban as alleged herein have substantially affected interstate and foreign commerce.

ANSWER: GSK denies the allegations in paragraph 124.

125. The relevant product markets are Wellbutrin SR arid Zyban and their generic bioequivalents rated "AB" by the FDA. The relevant geographic market is the United States. At all relevant times, including the present, Defendants' market share in the relevant product and geographic markets was and is 100%.

ANSWER: GSK denies the allegations in paragraph 125.

126. Plaintiffs incorporate by reference the preceding allegations.

ANSWER: GSK incorporates by reference its answers to the preceding allegations.

127. Pursuant to U.S. patent laws, Defendants were given a lawful monopoly over sales of prescription Wellbutrin products, but that monopoly was only lawful so long as the drug, or a method of its use, was fully covered by valid, unexpired patents.

ANSWER: GSK denies the allegations in paragraph 127.

128. Defendants knowingly and willfully engaged in a course of conduct designed to extend, unlawfully their monopoly power. This course of conduct included, *inter alia,* improperly filing and prosecuting a series of patent infringement actions against companies seeking to market an extended release bupropion hydrochloride product. Defendants' filing and prosecution of these actions was designed to delay the introduction of generic formulations of Wellbutrin SR and/or Zyban into the market and was in violation of Section 2 of the Sherman Act.

ANSWER: GSK denies the allegations in paragraph 128.

129. During the Class Period, Defendants possessed monopoly power in the relevant market. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. While obtaining and possessing its unlawful monopoly power over the market for Wellbutrin SR and Zyban Defendants set, maintained and raised

the price of Wellbutrin SR and Zyban to artificially high and/or supracompetive levels.

ANSWER: GSK denies the allegations in paragraph 129.

130. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of paying higher prices for Wellbutrin SR and/or Zyban products than they would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful. Plaintiffs and members of the Class are likely to purchase Wellbutrin SR and/or Zyban in the future. Injunctive relief is, therefore, appropriate under 15 U.S.C. § 26.

ANSWER: GSK denies the allegations in paragraph 130.

131. Plaintiffs seek to enjoin Defendants from engaging in future anticompetitive practices concerning the manufacture, distribution or sale of Wellbutrin SR and Zyban. Plaintiffs do not seek damages under Count I.

ANSWER: GSK admits that Plaintiffs seek the relief described in paragraph 131, but deny the implication that GSK has engaged or will engage in anticompetitive conduct.

132. Plaintiffs incorporate by reference the preceding allegations.

ANSWER: GSK incorporates by reference its answers to the preceding allegations.

133. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to extend their monopoly power. This course of conduct included, *inter alia*, improperly filing patent infringement actions against generic manufacturers seeking to obtain approval to sell generic versions of Wellbutrin SR and/or Zyban.

ANSWER: GSK denies the allegations in paragraph 133.

134. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Arizona Revised Stat. §§ 44-1401, *et seq.*,

with respect to purchases of Wellbutrin SR and Zyban in Arizona by members of the Class.

ANSWER: GSK denies the allegations in paragraph 134.

135. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases of Wellbutrin SR and Zyban in California by members of the Class.

ANSWER: GSK denies the allegations in paragraph 135.

136. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of D.C. Code Ann. §§ 28-45031, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in the District of Columbia by members of the Class.

ANSWER: GSK denies the allegations in paragraph 136.

137. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Fla.. Stat. §§ 501, Part II, *et. seq*., with respect to purchases of Wellbutrin SR and Zyban in Florida by members of the Class.

ANSWER: GSK denies the allegations in paragraph 137.

138. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Iowa law with respect to purchases of Wellbutrin SR and Zyban in Iowa by members of the Class.

ANSWER: GSK denies the allegations in paragraph 138.

139. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Kan. Stat. Ann. §§ 50-101, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Kansas by members of the Class.

ANSWER: GSK denies the allegations in paragraph 139.

140. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of La. Rev. Stat. §§ 51:137, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Louisiana by members of the Class.

ANSWER: GSK denies the allegations in paragraph 140.

141. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Maine by members of the Class.

ANSWER: GSK denies the allegations in paragraph 141.

142. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mass. Ann. Laws ch. 93, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Massachusetts by members of the Class.

ANSWER: GSK denies the allegations in paragraph 142.

143. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mich. CompLaws [sic] Ann. §§ 445.771, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Michigan by members of the Class.

ANSWER: GSK denies the allegations in paragraph 143.

144. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Minn. Stat. §§ 325D.52, *et seq.* with respect to purchases of Wellbutrin SR and Zyban in Minnesota by members of the Class.

ANSWER: GSK denies the allegations in paragraph 144.

145. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases of Wellbutrin and Zyban in Mississippi by members of the Class.

ANSWER: GSK denies the allegations in paragraph 145.

146. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Wellbutrin and Zyban in Nebraska by members of the Class.

ANSWER: GSK denies the allegations in paragraph 146.

147. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Nev. Rev. Stat. Ann. § 598A., *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Nevada by members of the Class.

ANSWER: GSK denies the allegations in paragraph 147.

148. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in New Jersey by members of the Class.

ANSWER: GSK denies the allegations in paragraph 148.

149. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.M Stat. Ann. §§ 57-1-1 *et seq*., with respect to purchases of Wellbutrin SR and Zyban in New Mexico by members of the Class.

ANSWER: GSK denies the allegations in paragraph 149.

150. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of New York General Business Law § 340, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in New York by members of the Class.

ANSWER: GSK denies the allegations in paragraph 150.

151. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in North Carolina by members of the Class.

ANSWER: GSK denies the allegations in paragraph 151.

152. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.D. Cent. Code § 51-08.1-01, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in North Dakota by members of the Class.

ANSWER: GSK denies the allegations in paragraph 152.

153. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in South Dakota by members of the Class.

ANSWER: GSK denies the allegations in paragraph 153.

154. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Tennessee by members of the Class.

ANSWER: GSK denies the allegations in paragraph 154.

155. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Vermont by members of the Class.

ANSWER: GSK denies the allegations in paragraph 155.

156. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in West Virginia by members of the Class.

ANSWER: GSK denies the allegations in paragraph 156.

157. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Wisconsin by members of the Class.

ANSWER: GSK denies the allegations in paragraph 157.

158. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR and Zyban prescription drugs than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Defendants' conduct unlawful.

ANSWER: GSK denies the allegations in paragraph 158.

159. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

ANSWER: GSK admits that Plaintiffs and the putative class seek damages for their alleged injuries. GSK denies that it has violated the aforementioned statutes and that Plaintiffs have been injured by any such alleged violations.

160. Plaintiffs incorporate by reference the preceding allegations.

ANSWER: GSK incorporates by reference its answers to the preceding allegations.

161. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they filed baseless patent infringement actions against Andrx and other generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Wellbutrin SR and Zyban. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Wellbutrin SR and Zyban.

ANSWER: GSK denies the allegations in paragraph 161.

162. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.

ANSWER: GSK denies the allegations in paragraph 162.

163. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.

ANSWER: GSK denies the allegations in paragraph 163.

164. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.

ANSWER: GSK denies the allegations in paragraph 164.

165. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq*.

ANSWER: GSK denies the allegations in paragraph 165.

166. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.

ANSWER: GSK denies the allegations in paragraph 166.

167. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.

ANSWER: GSK denies the allegations in paragraph 167.

168. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.

ANSWER: GSK denies the allegations in paragraph 168.

169. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq*.

ANSWER: GSK denies the allegations in paragraph 169.

170. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

ANSWER: GSK denies the allegations in paragraph 170.

171. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §10-1-392, *et seq*.

ANSWER: GSK denies the allegations in paragraph 171.

172. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.

ANSWER: GSK denies the allegations in paragraph 172.

173. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

ANSWER: GSK denies the allegations in paragraph 173.

174. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 174.

175. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.

ANSWER: GSK denies the allegations in paragraph 175.

176. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq*.

ANSWER: GSK denies the allegations in paragraph 176.

177. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq*.

ANSWER: GSK denies the allegations in paragraph 177.

178. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

ANSWER: GSK denies the allegations in paragraph 178.

179. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq*.

ANSWER: GSK denies the allegations in paragraph 179.

180. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*.

ANSWER: GSK denies the allegations in paragraph 180.

181. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq*.

ANSWER: GSK denies the allegations in paragraph 181.

182. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq*.

ANSWER: GSK denies the allegations in paragraph 182.

183. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.0 10, *et seq*.

ANSWER: GSK denies the allegations in paragraph 183.

184. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq*.

ANSWER: GSK denies the allegations in paragraph 184.

185. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq*.

ANSWER: GSK denies the allegations in paragraph 185.

186. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq*.

ANSWER: GSK denies the allegations in paragraph 186.

187. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 187.

188. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 188.

189. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 189.

190. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

ANSWER: GSK denies the allegations in paragraph 190.

191. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 191.

192. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. CODE § 51-15-01, *et seq*.

ANSWER: GSK denies the allegations in paragraph 192.

193. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq*.

ANSWER: GSK denies the allegations in paragraph 193.

194. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq*.

ANSWER: GSK denies the allegations in paragraph 194.

195. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq*.

ANSWER: GSK denies the allegations in paragraph 195.

196. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 196.

197. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 197.

198. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq*.

ANSWER: GSK denies the allegations in paragraph 198.

199. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. code Laws § 37-24-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 199.

200. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq*.

ANSWER: GSK denies the allegations in paragraph 200.

201. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq*.

ANSWER: GSK denies the allegations in paragraph 201.

202. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et seq*.

ANSWER: GSK denies the allegations in paragraph 202.

203. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq*.

ANSWER: GSK denies the allegations in paragraph 203.

204. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq*.

ANSWER: GSK denies the allegations in paragraph 204.

205. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in. violation of Wash. Rev. Code. § 19.86.010, *et seq*.

ANSWER: GSK denies the allegations in paragraph 205.

206. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq*.

ANSWER: GSK denies the allegations in paragraph 206.

207. Plaintiffs and members of the class members [sic] have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR and Zyban prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

ANSWER: GSK denies the allegations in paragraph 207.

208. Defendants have benefitted [sic] from the monopoly profits on their sales of Wellbutrin SR resulting from the unlawful and inequitable acts alleged in this Complaint.

ANSWER: GSK denies the allegations in paragraph 208.

209. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Wellbutrin SR and Zyban by Plaintiffs and members of the Class.

ANSWER: GSK denies the allegations in paragraph 209.

210. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

ANSWER: GSK denies the allegations in paragraph 210.

211. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Wellbutrin SR and Zyban is a direct and proximate result of Defendants' unlawful practices.

ANSWER: GSK denies the allegations in paragraph 211.

212. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

ANSWER: GSK denies the allegations in paragraph 212.

213. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Wellbutrin SR and Zyban derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

ANSWER: GSK denies the allegations in paragraph 213.

214. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

ANSWER: GSK denies the allegations in paragraph 214.

215. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

ANSWER: GSK denies the allegations in paragraph 215.

216. Plaintiffs and the Class have no adequate remedy at law.

ANSWER: GSK denies the allegations in paragraph 216.

WHEREFORE, Defendants respectfully request that this Court enter judgment in their favor on each of the Plaintiffs' counts, dismiss the Plaintiffs' claims in their entirety, and award Defendants costs, fees, and other such relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The Consolidated Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

Plaintiffs have not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in the Consolidated Complaint.

Third Affirmative Defense

At all times, GSK has acted in good faith and in furtherance of its legitimate business interests and has caused no injury to competition, the public, or the Plaintiffs.

Fourth Affirmative Defense

GSK's conduct is protected under the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States of America.

Fifth Affirmative Defense

GSK's conduct in submitting information on the subject patents to FDA for listing in the Orange Book was compelled by law.

Sixth Affirmative Defense

Plaintiffs' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act").

Seventh Affirmative Defense

Plaintiffs lack standing because they are not direct purchasers of Wellbutrin SR and/or Zyban.

Eighth Affirmative Defense

Plaintiffs lack standing under federal law.

Ninth Affirmative Defense

Plaintiffs lack standing under all or some of the state laws included in the Consolidated Complaint.

Tenth Affirmative Defense

GSK's conduct was lawful under the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the federal patent laws.

Eleventh Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because this action is not properly maintainable as a class action.

Twelfth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because there have been no class-wide damages as alleged by Plaintiffs.

Thirteenth Affirmative Defense

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, Plaintiffs' claims are barred, in whole or in part, to the extent that any higher prices were passed on, in whole or in part, to a third party payor not included in the putative class.

Fourteenth Affirmative Defense

Plaintiffs have an adequate remedy at law and no factual or legal basis exists for the grant of equitable relief.

Fifteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs would be unjustly enriched if they were allowed to recover all or any part of the damages alleged in the Complaint.

Sixteenth Affirmative Defense

Plaintiffs' alleged injury, if any, is the result, in whole or in part, of their own actions and contributory fault.

Seventeenth Affirmative Defense

Plaintiffs failed to mitigate any damages that they allegedly suffered.

Eighteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged damages, if any, are speculative.

Nineteenth Affirmative Defense

Plaintiffs' claims should be dismissed to the extent that they are moot.

Twentieth Affirmative Defense

GSK reserves the right to assert other defenses as discovery proceeds.

Twenty-First Affirmative Defense

GSK adopts by reference any and all additional applicable defenses asserted by any other defendant added at a later time.

Dated: August 29, 2003

Respectfully submitted,

_____

Mark S. Stewart
Leslie E. John
Ballard Spahr Andrews & Ingersoll, LLP
1735 Market Street, 51st Floor
Philadelphia, PA 19103
Telephone: (215) 665-8500
Facsimile: (215) 864-8999

William J. Baer
Kenneth A. Letzler
Cathy A. Hoffman
Amy R. Mudge
June Im
H. Holden Brooks
Arnold & Porter
Thurman Arnold Building
555 Twelfth Street, N.W.
Washington, D.C. 20004
Telephone: (202) 942-5000
Facsimile: (202) 942-5999

Timothy A. Thelen
Assistant General Counsel
GlaxoSmithKline
Five Moore Drive
Research Triangle Park, NC 27709
Telephone: (919) 483-1480
Facsimile: (919) 315-1044

Attorneys for GlaxoSmithKline PLC and SmithKline Beecham Corp. d/b/a GlaxoSmithKline

CERTIFICATE OF SERVICE

I certify that the foregoing Defendants' Answer to Plaintiffs' Consolidated Class Action Complaint was served on all counsel on August 29, 2003 as follows:

_____
Mark S. Stewart

VIA HAND-DELIVERY ONLY ON:

Anthony J. Bolognese
BOLOGNESE & ASSOCIATES, LLC
1617 JFK Boulevard, Suite 650
Philadelphia, PA 19103

Telephone: (215) 814-6750
Facsimile: (215) 814-6764

VIA OVERNIGHT MAIL AND FACSIMILE ON:

Thomas M. Sobol
Jeniene Andrews-Matthews
HAGENS BERMAN, LLP
225 Franklin Street
Boston, MA 02107

Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Marc A. Topaz
Krishna Narine
SCHIFFRIN & BARROWAY, LLP
Three Bala Plaza East
Suite 400
Bala Cynwyd, PA 19004

Telephone: (610) 667-7706
Facsimile: (610) 667-7056

J. Douglas Richards
Michael M. Buchman
MILBERG WEISS BERSHAD
HYNES & LERACH, LLP
One Pennsylvania Plaza
New York, NY 10119

Telephone: (212) 594-5300
Facsimile: (212) 868-1229

Christopher A. O'Hara
1301 5th Avenue, Suite 2900
Seattle, WA 98101

Telephone: (206) 623-7293
Facsimile: (206) 623-0594